G7 34 28
~~103~~. The method of claim ~~97~~ wherein at least one amino acid is a D-amino acid.--

REMARKS

Entry of the foregoing, reexamination and further and favorable reconsideration of the subject application in light of the following remarks, pursuant to and consistent with 37 C.F.R. § 1.112, are respectfully requested.

By the present amendment, claims 7, 14-15, 50, 52, 56 and 58 have been amended and new claims 90-103 have been added. Support for these amendments and new claims can be found throughout the originally filed application. No new matter has been added.

In the Official Action dated November 9, 1998, the Examiner defined species F as Phe-Glu-Gly, quite appropriately making no distinction between D or L amino acids. In reply to the Restriction Requirement, applicants elected species F. Claims reading on Phe-Glu-Gly, whether including D or L amino acids, then continued under prosecution.

The Examiner has now, with respect to this Continued Prosecution Application ("CPA"), applied applicants' previous election of the Group I claims and of the species F but has withdrawn claims 9, 53, 55, 59 and 61 which read on the elected species Phe-Glu-Gly, but relate to peptides which contain at least one D-amino acid. It is respectfully submitted that claims 9, 53, 55, 59 and 61 should be part of the group of claims under examination. Since there was not an undue burden to search and examine these claims in the pre-CPA application, there should be no undue burden at this time either.

The Examiner has rejected claims 7-8, 14-15, 38, 50, 52, 54, 56, 58, 60 and 62-63 under 35 U.S.C. § 112, second paragraph, as being indefinite for purportedly failing to

particularly point out and distinctly claim the subject matter which applicants regard as the invention. This rejection is respectfully traversed.

In order to expedite prosecution, and not acquiesce to the Examiner's rejections, the wording of these claims has been clarified by amending claims 7, 14, 15, 52 and 58 to delete "a sequence of" from the definition of R^2. All of these claims, as amended, are allowable. Moreover, the claim amendments are not intended to narrow the scope of any claim element(s) and/or limitation recited therein.

In view of the above, withdrawal of this rejection under 35 U.S.C. § 112, second paragraph, is respectfully requested.

The Examiner has rejected claims 50, 52, 54, 56, 58, 60 and 62-63 under 35 U.S.C. § 112, first paragraph, on the grounds that the specification, while enabling these claims with respect to the peptide FEG, allegedly does not enable them for peptides of the formula R_1 -X_1 -X_2 -R_2. This rejection is respectfully traversed.

The Examiner has asserted that the specification exemplifies only a single peptide, FEG, as useful in the claimed methods. Applicants respectfully disagree.

Claim 15 is directed to a method of reducing or preventing an anaphylactic reaction in a mammal by administering a peptide of the defined formula R^1 -X^1 -X^2 -R^2. The specification describes a number of experiments which examine the inhibitory effect of peptides falling within this formula on an anaphylactic reaction.

Example 3 (page 22 and Figure 3) shows the prevention of an intestinal anaphylactic reaction to a challenge antigen by the peptide SGP-T (SEQ ID NO:8). This

same model of anaphylactic reaction was used in Example 6 which demonstrated that the peptides SGP-T (TDIFEGG), TAIFEGG, TDAFEGG, FEGG and FEG inhibited the anaphylaxis (see Table 2, page 37).

Example 7, using the same model, further demonstrated that the peptides TDIFAGG and FESarcosine, in addition to those listed above, were effective to prevent an anaphylactic reaction (Tables 3 and 4, page 38).

Example 9 (page 29) demonstrated that peptide feG was also effective to prevent an anaphylactic reaction.

Applicants have, therefore, demonstrated the efficacy of a number of peptides within the formula of claim 15 and essentially all of the peptides of claim 56.

Claim 14 is directed to a method of treating or preventing anaphylactic hypotension by administering a peptide of the defined formula.

Example 3 (page 22) shows the prevention of anaphylactic hypotension by the peptide SGP-T (TDIFEGG) and Example 8 extended this observation to the peptides FEG and feG (Figures 9 and 10). Furthermore, all of the peptides demonstrated to be effective in reducing or preventing an anaphylactic reaction, as discussed above, would be expected also to be effective in treating or preventing anaphylactic hypotension.

Contrary to the case of *Ex Parte Sudilovsky*, 21 U.S.P.Q.2d 1702 (B.P.A.I. 1991), where the applicant did not provide any exemplification, the instant application has provided many examples and is not "confined to broad allegations and suggestions" as asserted by the Examiner. One of skill in the art can readily determine, using an assay

such as the anaphylaxis model described in the examples, whether a particular peptide within the general formula of claim 14 or claim 15 is effective to prevent or reduce an anaphylactic reaction. As in *In re Wands*, 8 U.S.P.Q.2d 1400 (Fed. Cir. 1988), cited by the Examiner, the instant disclosure "provides considerable direction and guidance on how to practice [the] invention and presents working examples" and no undue experimentation would be required to practice the invention.

In view of the above, the Examiner is respectfully requested to withdraw this rejection under 35 U.S.C. § 112, first paragraph.

The Examiner has rejected claims 7-8 and 38 under 35 U.S.C. § 102(b) as purportedly being anticipated by Slootstra et al. which teaches the peptide Phe-Glu-Gly. This rejection is respectfully traversed.

To expedite prosecution in the subject application, and not to acquiesce to the Examiner's rejection, claim 7 has been amended to delete "glycine". The cited reference does not anticipate these claims, as amended. Accordingly, the Examiner is respectfully requested to withdraw this rejection under 35 U.S.C. § 102(b).

Finally, as noted above new claims 90-103 have been added to more fully protect applicants' invention. These claims are directed to methods employing more specifically defined peptides within the formula of claims 14-15.

From the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order. Such action is earnestly solicited.

In the event that there are any questions relating to this Amendment and Reply, or to the application in general, it would be appreciated if the Examiner would telephone the undersigned attorney concerning such questions so that prosecution of this application may be expedited.

Respectfully submitted,

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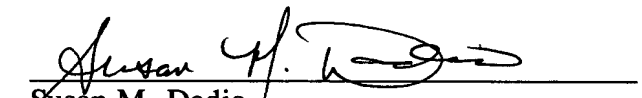
By: 
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Date: November 19, 2001

Attachment to Amendment and Reply dated November 19, 2001

Marked-up Claims 7, 14-15, 50, 52, 56 and 58

7. (Three times amended) A peptide of the formula: R^1-X^1-X^2-R^2

wherein X^1 is an aromatic amino acid residue;

X^2 is any amino acid residue; and

R^1 is NH_2- or an amino acid sequence X^3-X^4-X^5

wherein X^3 is an aliphatic amino acid residue having a side chain hydroxyl group and X^4 and X^5 are the same or different and are any amino acid residue and wherein R^2 is [a sequence of] 1 to 3 amino acid residues which are the same or different and are selected from the group consisting of [glycine,] sarcosine, azetidine, nipecotic acid and pipecotic acid.

14. (Three times amended) A method for treating or preventing anaphylactic hypotension in a mammal comprising administering to the mammal an effective amount of a peptide of the formula: $R^1 - X^1 - X^2 - R^2$

wherein X^1 is an aromatic amino acid residue;

X^2 is any amino acid residue; and

R^1 is NH_2- or an amino acid sequence $X^3 - X^4 - X^5$

wherein X^3 is an aliphatic amino acid residue having a side chain hydroxyl group and X^4 and X^5 are the same or different and are any amino acid residue and wherein R^2 is

[a sequence of] 1 to 3 amino acid residues which are the same or different and are aliphatic amino acid residues or of an effective fragment or derivative of said peptide.

15. (Three times amended) A method of reducing or preventing an anaphylactic reaction in a mammal comprising administering an effective amount of a peptide of the formula: $R^1 - X^1 - X^2 - R^2$

wherein X^1 is an aromatic amino acid residue;

X^2 is any amino acid residue; and

R^1 is NH_2- or an amino acid sequence $X^3 - X^4 - X^5$

wherein X^3 is an aliphatic amino acid residue having a side chain hydroxyl group and X^4 and X^5 are the same or different and are any amino acid residue and wherein R^2 is [a sequence of] 1 to 3 amino acid residues which are the same or different and are aliphatic amino acid residues or of an effective fragment or derivative of said peptide to the mammal.

50. (Amended) The method of claim 14 wherein

X^1 is phenyl alanine;

X^2 is Glu or Ala;

R^2 is selected from the group consisting of Gly, Gly-Gly and Gly-Gly-Gly; and

R^1 is NH_2- or $X^3 - X^4 - X^5$ wherein

X^3 is Thr, X^4 is Asp or Ala and

X^5 is Ile or Ala.

52. (Amended) The method of claim 14 wherein R^2 is [a sequence of] 1 to 3 amino acid residues which are the same or different and are selected from the group consisting of glycine, sarcosine, azetidine, nipecotic acid and pipecotic acid.

56. (Amended) The method of claim 15 wherein

X^1 is phenyl alanine;

X^2 is Glu or Ala;

R^2 is selected from the group consisting of Gly, Gly-Gly and Gly-Gly-Gly; and

R^1 is NH_2- or $X^3 - X^4 - X^5$ wherein

X^3 is Thr, X^4 is Asp or Ala and

X^5 is Ile or Ala.

58. (Amended) The method of claim 15 wherein R^2 is [a sequence of] 1 to 3 amino acid residues which are the same or different and are selected from the group consisting of glycine, sarcosine, azetidine, nipecotic acid and pipecotic acid.